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CHARDACK-GREATBATCH IMPLANTABLE CARDIAC PACEMAKERS

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35

ENDOCARDIAC AND MYOCARDIAL SYSTEMS

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CHARDACK-GREATBATCH
IMPLANTABLE CARDIAC PACEMAKERS

MODEL 5870-C
and Special Models
5852, 5860, 5860-C and 5868

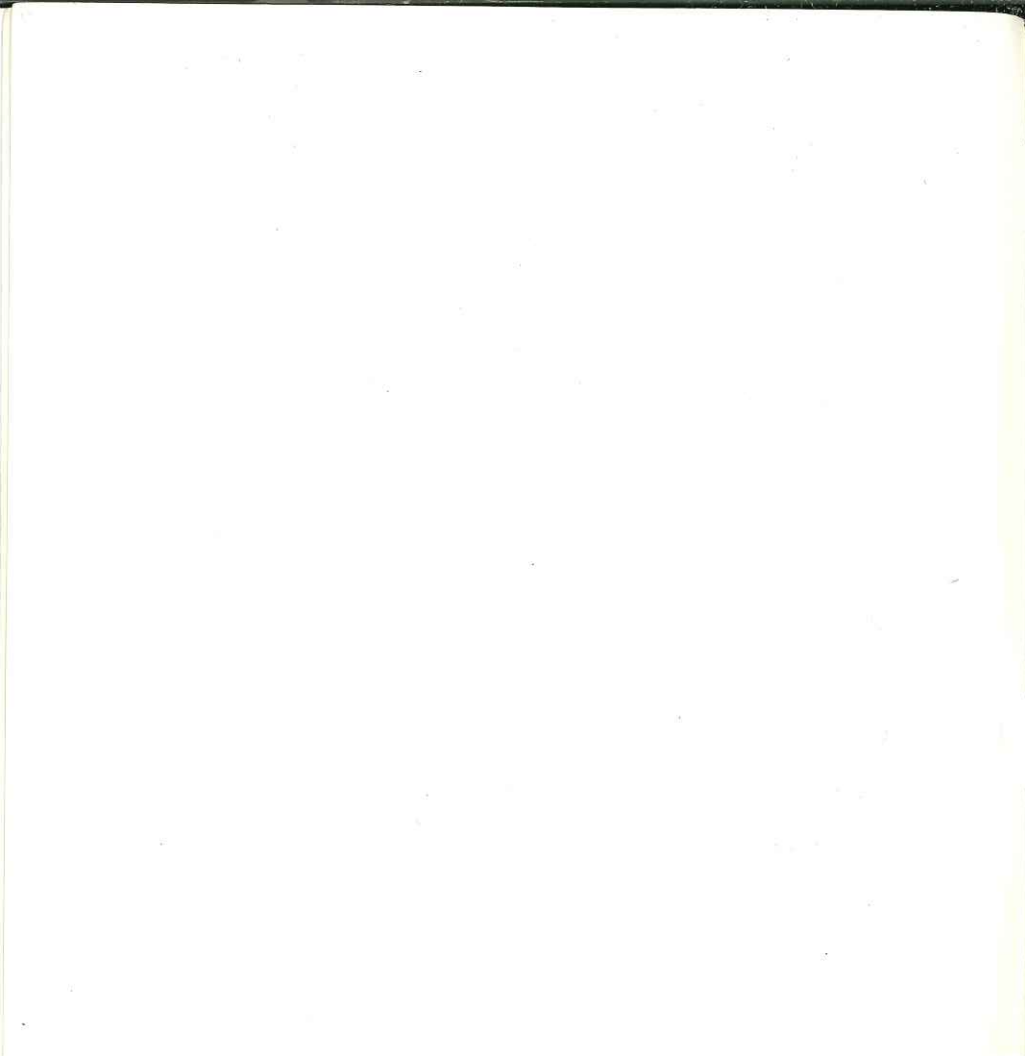
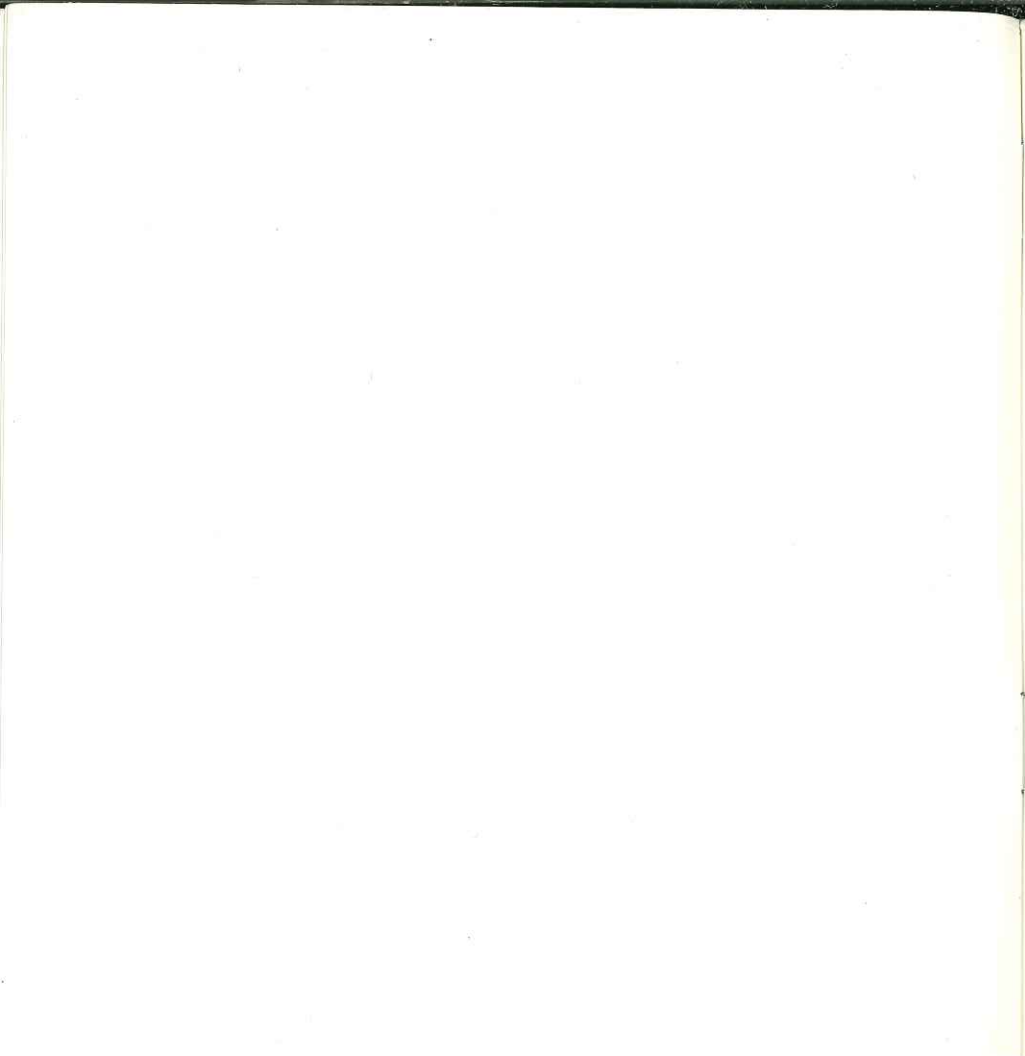


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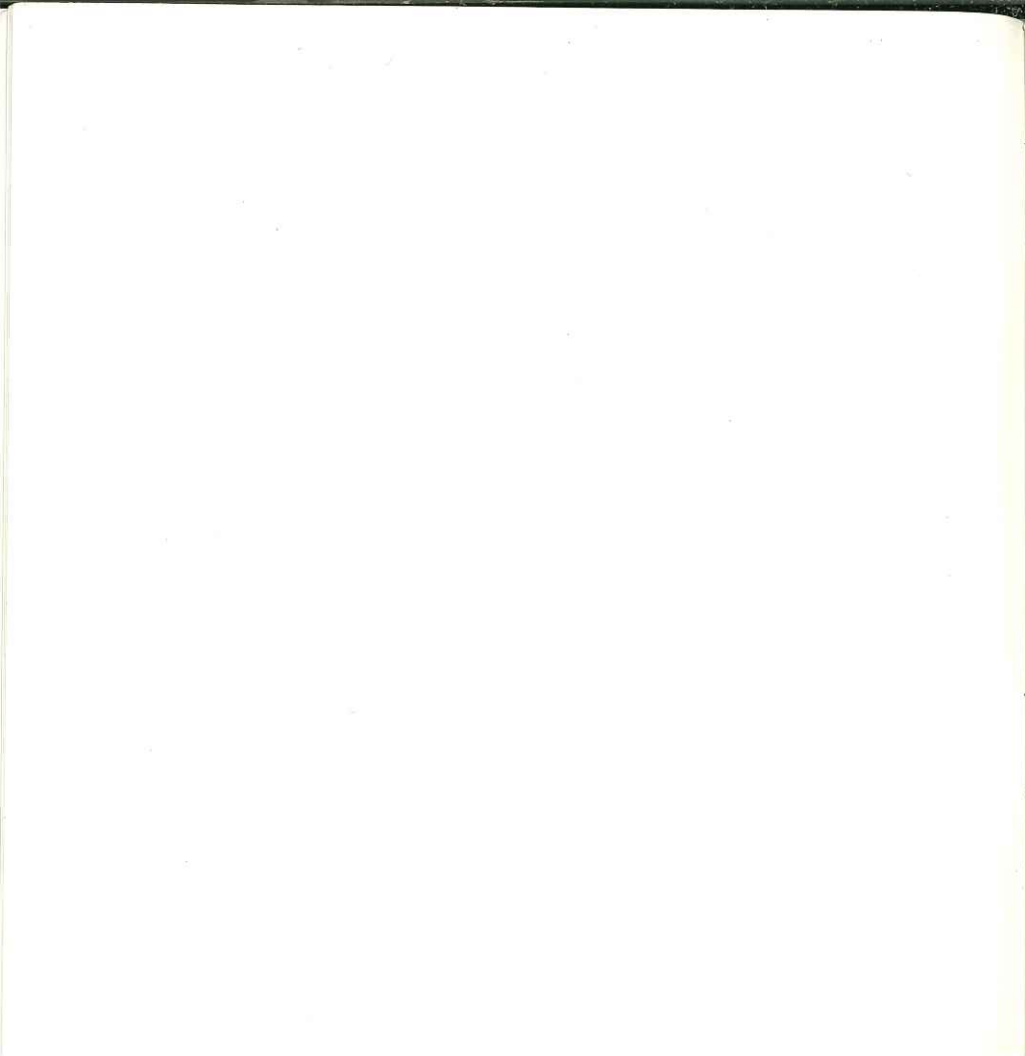


HANDLING, STERILIZATION

The components of the pulse generator are encapsulated in epoxy resin, and the unit is covered with medical grade silicone rubber, chosen for its inertness in tissue. Silicone rubber has an electrostatic affinity for surface contaminants, such as dust, lint, talc, etc. To prevent inclusion or adherence of any foreign particles, the pacemaker has gone through final assembly and packaging operations in a conditioned room providing control over particles in the environment. The package includes a double wrap of sealed, gas-permeable plastic. After packaging and sealing, the unit is gas sterilized by ethylene oxide (a color tape indicating sterilization is visible in the package). Medtronic implantable systems are not shipped until a registered bacteriologist certifies that spore strips of *Bacillus subtilis globigii* included in the sterilization batch (inside a pacemaker package) have yielded no growth.

Ordinarily no further handling or cleaning is required prior to use. If the package has been damaged during transportation, it must be resterilized. If this is necessary, ethylene oxide gas should be used and the temperature should not exceed 60°C (145°F). At least 24 hours should elapse between sterilization and use of the unit in order to permit complete escape of the gas. *The pulse generator should not be autoclaved.*

The myocardial electrode package contains a square of polyvinyl alcohol sponge, for use over the electrode heads (as described on page 27). If sterilization of this sponge is necessary, it may be sterilized by dry steam (autoclave) which will lead to 15%-20% shrinkage. The cooled sponge may be wrung out under sterile conditions and prepared for use by soaking in sterile isotonic solution. Some authorities infuse with penicillin before insertion.



THE PULSE GENERATOR

The Model 5870-C pulse generator is shown in Figure 2 and the frontispiece. The polarity of the pulse generator terminals is indicated by plus and minus signs molded in the epoxy of the pulse generator body. The current or "amplitude" control is closest to the electrode terminals and is identified by the letter "A" molded in the epoxy. The rate control is marked with the letter "R".

The pulse generator provides a biphasic pulse of 1.8 milliseconds duration. Output pulse characteristics into a test load are shown in Figure 1. In actual operation the wave shape depends on cardiac impedance.

ALL DETERMINATIONS
MADE INTO:

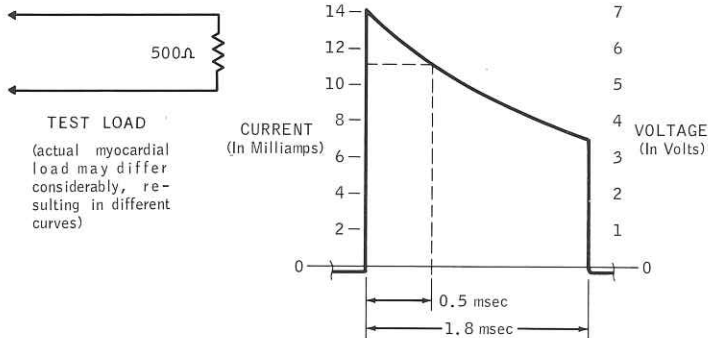


Figure 1. Typical Output Pulse Characteristics into Test Load

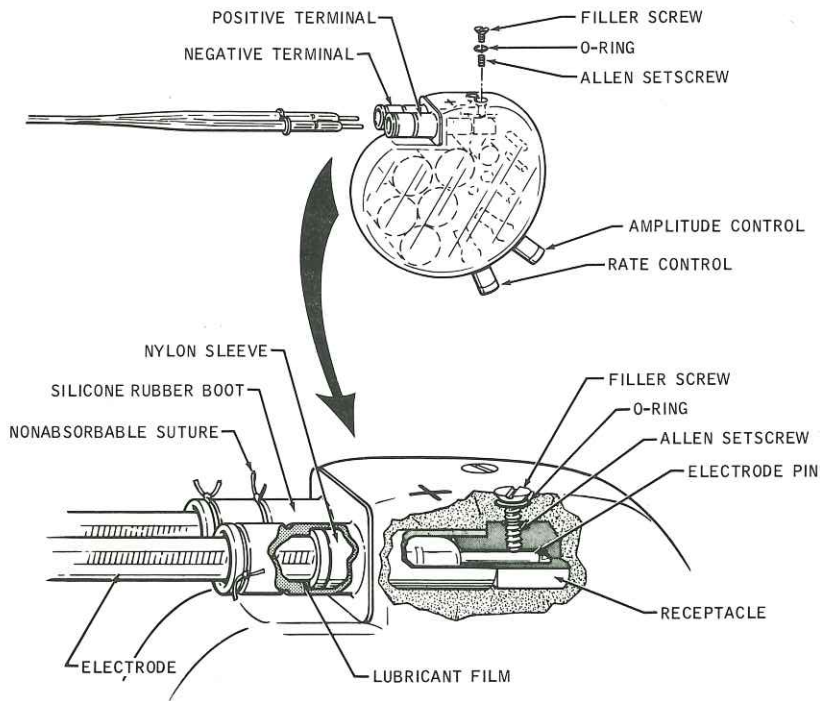


Figure 2. Electrode-Pulse Generator Connection.

CONNECTING ELECTRODES TO PACEMAKERS

Implantable Pulse Generators

The connection of the electrode to the pulse generator is illustrated in the adjacent Figure. The electrode terminal should be coated with silicone lubricant and then pushed into the receptacle of the pulse generator until the collar on the terminal snaps into place on top of the nylon sleeve in the silicone rubber boot. This boot has a neck-like contour. The collar of the terminal, when completely secured, should lie about 2 to 3 mm within the neck of the boot. With the pin in this position, the*preinserted Allen screw should be tightened with the Allen wrench. The self-sealing screw should then be inserted over the Allen screw.

The boots should be tied with non-absorbable sutures. The pacemaker can be implanted immediately after suturing. No further waiting is required.

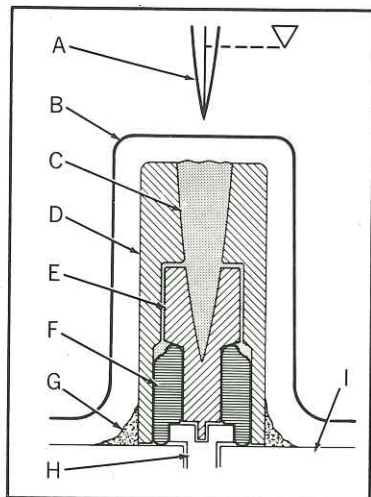
*Allen screws are now inserted at the factory prior to shipment.

Description of Controls

A cross-section of the current and rate controls is diagrammed in Figure 3. The slotted shafts (H) of these controls have been fitted with special rotating adaptors (E). The top of each adaptor has a socket of triangular cross-section which will accept a "Keith" surgical skin needle* (A), of triangular cross section. A stainless steel housing (D) fits over this adaptor, and the tunnel in the top of this housing guides the needle point into the adaptor.

Figure 3. Cross-section, Control Shaft Receptacle

- (A) Keith skin needle
- (B) Silicone rubber, continuous with pulse generator encapsulation
- (C) Silicone grease
- (D) Stainless steel housing and needle guide
- (E) Adaptor
- (F) Silicone rubber pressure gasket
- (G) Epoxy seal
- (H) Shaft of variable resistor
- (I) Housing of variable resistor



*Anchor, 2½ in. straight skin needle to which a handle has been attached; supplied with the pacemaker.

The assembly is shielded against penetration of body fluids by:

- An outer silicone rubber covering (B).
- Silicone lubricant in the potentiometer and between all parts of the assembly (C).
- A silicone rubber gasket (F).
- A neoprene seal on the shaft of the potentiometer.

Adjustment of output pulse rate or current can be made before or after implantation. The sterile needle is inserted into the apex of the control. Clockwise rotation increases current or rate. If adjustment is required after implantation, the protruding controls are palpated beneath the skin and identified by their position with respect to the electrode terminals. The skin over the control is rendered sterile and the Keith needle is inserted into the apex of the protrusion. Insertion of the needle may be facilitated by infiltration of the skin with a few drops of local anesthetic. Rotation of the needle may be made easier by lubricating the tip with sterile mineral oil.

Rate Control

The rate control is a linear 42-turn potentiometer, spanning a range from 55 to 120 beats per minute. This provides a change in rate of $1\frac{1}{2}$ beats per turn. It is preset by the manufacturer to a rate around 70 (unless otherwise ordered). The control has a null position occupying 2 turns, lying between the maximum and minimum rate positions. There is no stop at the null position-the control may be continuously turned up to maximum, into and through the null position, entering the minimum range again. In the null position the pacemaker is turned off. Figure 4 illustrates the mode of operation of this control.

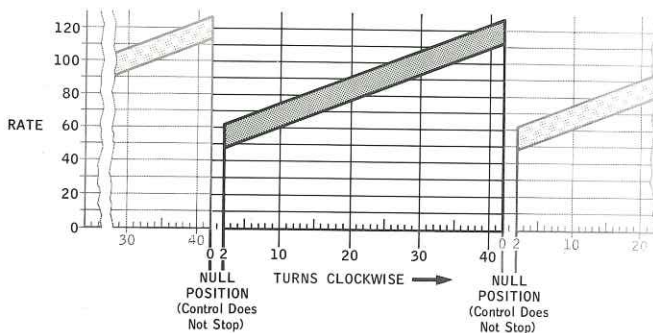


Figure 4. Pulse Rate Range, vs Rate Control Setting

Current Control

The output current is controlled in nonlinear fashion by a 42-turn, 10 000-ohm potentiometer connected in series with the output of the

pulse generator. This control also has a null position occupying 2 turns, lying between the maximum and minimum points (Figure 5).

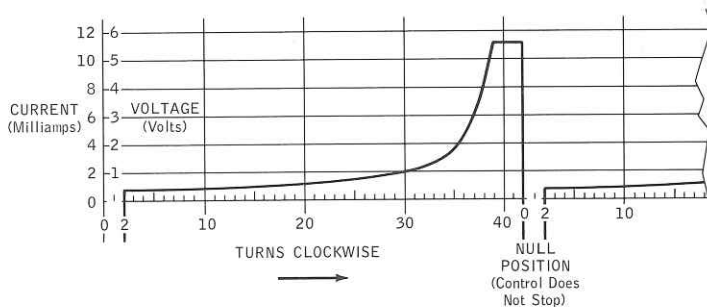


Figure 5. Output Current into Test Load, vs Control Setting

The output has been set to full during manufacture of the pulse generator.* After the electrode has stabilized (four to six weeks following implantation), the output may be adjusted to about twice the threshold value. This reduces the current drain and eliminates the large margin which a fixed-output pulse generator must supply to cover the range of current requirements encountered.

*Pulse generators ordered with myocardial electrodes (Myocardial Pacemaker Model 5870) have the output set at 4.5 ma.

The technique of adjustment of the pulse current is illustrated in Figures 6 and 7. The electrocardiogram is monitored. The threshold of stimulation is determined by turning the current control counter-clockwise until capture is lost; as this is done, turns are counted by observing the position of the dot on the handle of the "Keith" needle. If the threshold is approached gradually, alternate stimuli will usually be followed by a QRS (Figure 6A). If the threshold is reached abruptly, a period of asystole ensues before the patient's idioventricular pacemaker resumes activity (Figure 6B). In some patients, even at slow rates of pacemaking, this period of asystole may last several seconds. Longer lags may be encountered and may require return to pacemaking by immediate clockwise rotation of the needle.

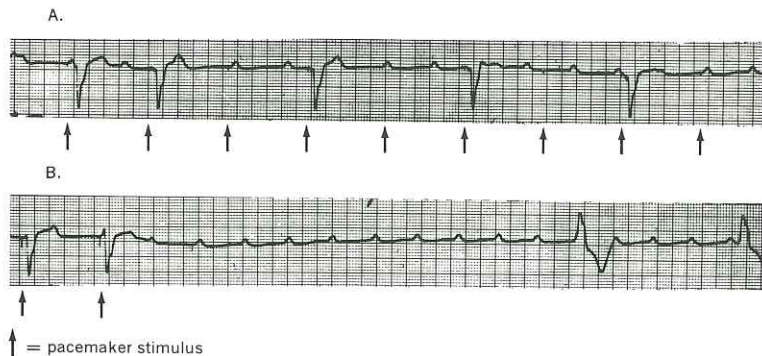


Fig. 6A. Pacemaker output is near threshold of stimulation. Only every other pulse if followed by a QRS.

6B. Pacemaker output is below threshold. A period of asystole occurs before the idioventricular rhythm resumes.

After the threshold has been determined, its approximate position on the graph in Figure 7 is identified. Since the pulse generator had initially been set to full output (corresponding to 39 turns, Figure 7), the number of counter-clockwise turns required to reach threshold serves to place it on the graph (ie, in the example shown in Figure 7, 15 counter-clockwise turns puts the threshold current at about 1.5 ma). The stimulus amplitude is then set at approximately twice the threshold value (about 3 ma) by advancing the current control 10 clockwise turns.

EXAMPLE:

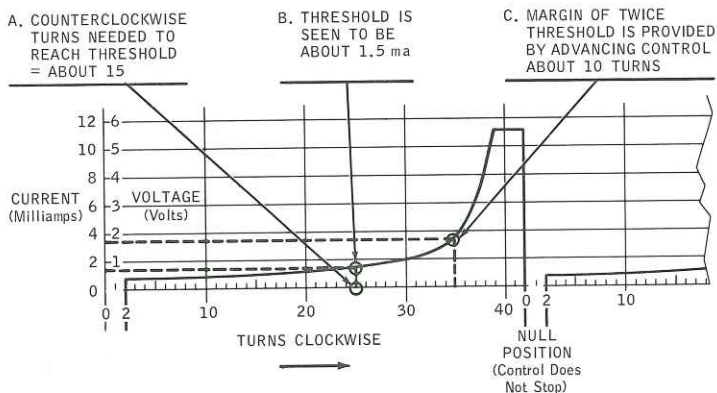


Figure 7. Adjustment of Current Control

Pulse Generator Life

Battery capacity, current drain, and performance of the electronic components are the factors governing service life. The mercury cells* in the pulse generator are rated at 1000 milliampere-hours, with a shelf life of 5 years or more. This capacity, calculated against the average current drain, is adequate to power the pulse generator for several years. When pacemakers were first introduced, premature battery failure was a common cause of pulse generator malfunction. Battery reliability is now higher, and premature battery failure is rare.

The pulse generator produces pulses at a rate that is relatively independent of supply voltage; exhaustion of one cell will increase the rate by about 2 beats/minute. Exhaustion of additional cells will produce further small increments in the rate, but the output current will also be reduced, disabling the pulse generator before an excessive increase in the stimulation rate can occur.

Detailed observations on the performance and reliability of the components and of the system as a whole have been the subject of recent publications.^{1,2} We feel strongly that such data should be available to the medical profession, since it may influence the management of the patient. For this reason, reliability reports on Chardack-Greatbatch pacemakers have been and will be disseminated to physicians and surgeons who use this equipment. Recommendations will be made on a suggested service life and the elective replacement of pulse generators at appropriate intervals. These recommendations will be based on data on the past performance of a given generation of pacemakers, and will be aimed to yield a 90% or better probability of failure-free performance

*"Certified Cells"; P.R. Mallory Company; Indianapolis, Indiana.

for the interval recommended. Reliability data on the performance of several thousand pulse generators manufactured between January and December 1964 (units which now have seen considerable exposure) indicate a recommended service life of 30 months for these units. The upper limit of service life that can be recommended for pulse generators manufactured after December of 1964 is expected to exceed 30 months. Specific recommendations on the service life of this generation of units will be made as further data accumulate.

We wish to emphasize to the users of this equipment, physicians as well as patients, that although no effort is spared in the procurement and pretesting of components of the highest available quality, such components do have a low but finite incidence of failure.

It must also be emphasized that failure of certain critical components in any presently known pacemaker can lead to excessive increases in the rate.^{3,5,14} Again, such instances are now very rare, but physicians and patients must be aware of this possibility. Patients must be taught to take a two-minute pulse rate twice a day. Any change in the rate should be reported. Any change of more than 5 beats, which the electrocardiogram shows to be a change in the stimulation rate, is evidence of malfunction of the unit. Any excessive increase in the rate is an acute emergency and calls for immediate disabling of the pacemaker.

The 5870-C pulse generator can be turned off by rotating the current control counter-clockwise until the output of the unit falls below the threshold of stimulation. When electrical pacing of the heart is suddenly interrupted (especially when pacing at high rates), long periods of asytle are apt to occur, and a battery-powered external pacemaker (Model 5800) should be ready.

Influence of External Electrical Fields on Implanted Pacemakers

The effects of electrical fields in the environment on pacemaker performance have been the topic of several recent reports. The following observations have been made by us on pacemakers of our design. These observations pertain to *completely implanted units* - whether or not the unit is implanted is critical in regard to the electrical coupling which occurs.

The rate and output are not altered by:

- Proximity to automobile ignition systems and sparkplugs.
- External defibrillating shocks.
- X-radiation at diagnostic or therapeutic levels of exposure.
- Electrocautery cutting currents.
- Proximity to incandescent, fluorescent, or neon lights.

Rate and output are adversely affected by:

- Electrocautery coagulating currents if the cautery tip is within 2 inches of the pacemaker's pulse generator.
- Placing a diathermy drum or coil over the area in which a pacemaker pulse generator is implanted.

The foregoing material was drawn from data gathered by the manufacturer and abstracted from the references listed in this manual.

ENDOCARDIAC SYSTEMS

Comments on the Operative Procedure*

In patients with clearly established indications, installation of the permanent endocardiac system can be carried out as the initial therapeutic step, since the procedure carries virtually the same risk and requires but little more time than the insertion of a temporary endocardiac electrode. *Provisions for monitoring, external pacemaking, and defibrillating must be made.* Support of the heart rate during insertion of the electrode is required in only a few patients and rarely for more than a few minutes. Control of the heart rate can usually be obtained by an intravenously administered solution of isoproterenol (1 mg in 500 cc of normal saline) and external pacemaking is seldom needed. The rate of administration of the isoproterenol solution must be carefully titrated to avoid myocardial irritability. Used with caution on such a short-term basis, isoproterenol has been satisfactory in our hands. However, it must be emphasized that *myocardial irritability, tachyarrhythmia and ventricular fibrillation during insertion of the electrode are very likely to be a problem in patients who have been on intravenous isoproterenol for prolonged periods of time prior to the procedure.* As soon as the heart is pacemaded, myocardial irritability can be suppressed by the intravenous administration of procaine amide or other antiarrhythmic agents.

In patients in whom the use of a temporary endocardiac electrode is indicated but in whom the later use of a permanent system can be anticipated, the right external jugular vein should be spared since (in our hands) it has been the preferential site for placement of the permanent electrode. The temporary system should be installed through the

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left external jugular vein and left in place until installation of the permanent system has been completed and secure pacing through it has been demonstrated.

Manipulation and positioning of the electrode are greatly facilitated by an image intensifier; the entire procedure can be performed in the cardiac catheterization room. Conventional fluoroscopy is unsatisfactory in regard to positioning of the electrode, maintenance of a sterile field, observation of the patient, and the ability to cope with emergencies.

Electrode Placement

Under local anesthesia, the right external jugular vein is exposed; if this vessel is unavailable or is too small, the right internal jugular, one of the left jugulars, or the cephalic vein on either side can be used. The electrode, with the stylets reinserted after imparting a slight curvature to their distal portion, is inserted into the vein, advanced to the right ventricle, and wedged in the trabeculations of the apex. In some cases, it may be helpful to partially withdraw the stylets after the tip of the electrode has just passed the tricuspid valve. This maneuver leaves the distal 5 to 7 cm of the electrode flexible, and it tends to move towards the bottom of the ventricle. The stylets are then advanced again into the tip and wedging is completed.

Accurate positioning and wedging of the electrode is essential for stable pacemaking with this technique. In order to obtain secure capture of the cardiac rhythm, direct contact or very close proximity of one of the terminals to the endocardium is required.

Generally, a satisfactory position can be achieved either with the tip of the electrode pointing straight towards the apex (Figure 9) or with the distal end of the electrode making a slight dip or bend, suggesting that it is curving around a trabeculation (Figure 10, bottom). In some cases, stable positions have been associated with configurations that deviate from these two patterns.



Figure 8. Markings indicate subcutaneous position of pulse generator and electrode.

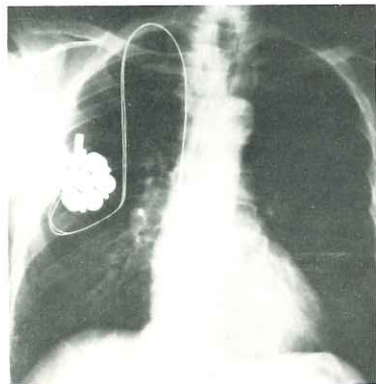


Figure 9. A-P chest x-ray of patient with implanted pacemaker system (leads retouched for reproduction).

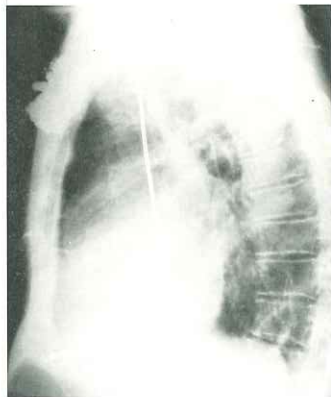


Figure 10. Lateral chest x-rays of patients with implanted endocardial electrodes. Bend in distal tip assumed to be due to electrode curving around trabeculation.

Threshold Determination, Verification of Placement

Stimulation thresholds must be determined by using a battery-driven pacemaker^{17, 18} with a calibrated output current control to verify the adequacy of the electrode's position and contact with the endocardium. This pacemaker may be placed outside the sterile field and connected to the electrode terminals with sterile clip leads. Cathodal stimulation threshold is first determined; Then the electrode terminal leading to the tip (identified by marking rings around the conductor coil in the silicone rubber of the terminal plug) is connected to the negative output terminal of the external pacemaker. The circuit is completed by attaching the clip lead from the positive terminal of the pacemaker to the subcutaneous tissues or to a hemostat in contact with the tissues. Current is reduced until capture is lost, and the milliamperere value is noted. The same procedure is then repeated for the ring terminal. Usually contact with the endocardium (hence, the low threshold reading) occurs at the tip; however, in about one-fifth of the cases, contact (and low threshold reading) occurs at the ring, or equally low threshold current values are found at both terminals. With this electrode, a threshold current of 1.5 milliamperes or less is indicative of good position and satisfactory endocardiac contact. Some values above this level may still be acceptable. Thresholds in excess of 2.5 milliamperes should not be accepted-the electrode should be repositioned until a lower value is found.

After a satisfactory position has been achieved *both stylets are completely withdrawn*, and the vein is tied off around the electrode with nonabsorbable suture material. The thresholds are then checked again and maintenance of capture is verified with the patient's position changed as much as possible within the limitations imposed by the sterile field. Loss of capture with change in position requires readjustment of the electrode.

The importance of a satisfactory position of the electrode cannot be overemphasized. Wedging into the trabeculae is essential in obtaining a low threshold and minimizing dislodgement of the tip. In an occasional patient it may be impossible to reach a satisfactory position; thoracotomy and insertion of myocardial electrodes should then be considered.



Figure 11. Tip of Electrode Wedged into Apex of Right Ventricular Cavity. Note Numerous Trabeculae Carneae.

Pulse Generator Implantation

After completing electrode insertion, a second incision is made below the medial portion of the clavicle (Figure 8), and a tunnel is formed between the two incisions at the level of the fascia beneath the subcutaneous layer of fat. The electrode terminals are passed through the

tunnel and attached to the pulse generator; the negative pulse generator terminal is attached to the terminal of the electrode which has exhibited the lower threshold for cathodal stimulation (as determined previously). The connection between the electrode terminals and the pulse generator is completed as described on page 5.

A subcutaneous pocket is then formed for the pulse generator beneath the medial portion of the clavicle. In patients in whom an adequate adipose layer is not available, the pulse generator is placed beneath the pectoralis major; a more lateral retropectoral placement of the pulse generator also can be used, especially when the electrode is introduced

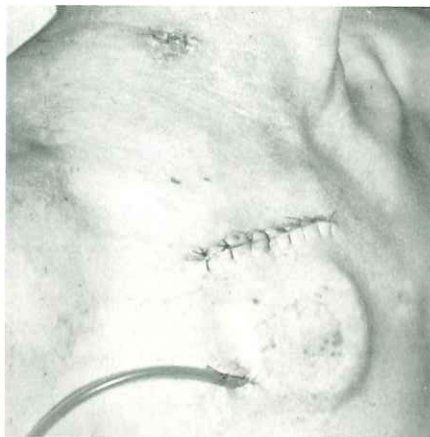


Figure 12. Shortly after completion of procedure

through the cephalic vein.^{6, 15} The pocket is drained under mild suction for 24 hours by a catheter brought out through a separate stab wound. Anticoagulants are not required, but protection against staphylococcus by the prophylactic administration of staphicillin is recommended.

Concluding

Loss of position of the electrode in the postoperative periods is the principal complication associated with this technique. The incidence is of the order of 10 percent. Almost always, dislodgement occurs within the first two weeks following insertion, and most often within the first few days. It is usually possible to correct this complication by repositioning the electrode under local anesthesia. The potential seriousness of this complication warrants monitoring of the electrocardiogram for a few days at least, and longer if this can be done by techniques compatible with ambulation of the patient.

Myocardial irritability, ectopic activity, and tachyarrhythmias have been much less of a problem in patients treated with the endocardiac electrode than in those who were managed by thoracotomy and insertion of myocardial electrodes. However, such phenomena do occur and require suppression. In most instances this can be obtained by the administration of procaine amide and correction of electrolyte imbalance, particularly in regard to potassium. In some cases a temporary increase in the stimulation rate may be essential to control multifocal ectopic activity.



MYOCARDIAL ELECTRODES

Comments on the Operative Procedure*

Preoperative Procedure

Difficulties with cardiac arrhythmias and arrest are most likely to occur during induction of anesthesia, intubation, and the initial stages of the thoracotomy. One must, therefore, be in a position to pacemake the heart prior to the induction of anesthesia. This can be accomplished either (1) by introduction of a catheter electrode into the right ventricle, or (2) by an external pacemaker with the electrodes taped on the chest wall in a position such that they will not interfere with the sterile field. The preoperative use of a catheter electrode is now finding widespread acceptance and we have come to employ it routinely. It permits continuous preoperative pacing, leisurely preparation of the patient, and absolute control of the heart rate during the procedure, without the muscle contractions associated with the use of external chest wall electrodes. Again, only battery-driven pacemaking equipment should be used on cardiac electrodes, endocardiac or myocardial, temporary or permanent. If a catheter electrode is not available and if an external pacemaker is relied upon, it is recommended that provision be made to maintain the heart rate by direct stimulation once the myocardium has been exposed. This can be done conveniently by bringing two sterile lead wires, connected to a battery-powered pacemaker, into the operative field. One lead is attached to any instrument in the field which is in constant contact with the exposed tissue—for instance, a rib spreader. The other lead is connected to a hemostat. By lightly touching the surface of the

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heart with the latter, stimulation is obtained without the chest wall muscle stimulation and contractions entailed by the use of an external pacemaker with chest electrodes.

Continuous monitoring of the electrocardiogram is indicated, and an intravenous drip of a solution containing procaine amide should be in place and ready for use.

Operative Procedure - Incisions and Tunneling

An anterolateral approach through the fourth or fifth interspace or through the bed of the resected fifth rib gives adequate exposure to the left ventricular myocardium.

After exposure of the heart, the thoracic incision is temporarily abandoned and a 3-in. long incision is made in the left upper quadrant of the abdomen, close to the midline. A subcutaneous tunnel is then formed by blunt dissection between the abdominal and thoracic incisions. This tunnel should be quite ample in dimensions to permit easy passage of the electrodes. It is recommended that the electrode terminal plugs be passed from the thoracic incision down to the abdominal incision in order to prevent inadvertent damage to the electrode heads. If the heads are passed through the tunnel, the plastic protective caps should be left in place over the tips.

Placement of Electrode Heads

The electrode heads should be placed side by side on an avascular area of the left ventricular myocardium. If such an area can be found near the apex, this may be preferable to a more basal site, since there is evidence to suggest that activation of contraction from an apical site may be more effective.⁹ However, this opinion is not shared unanimously and, in general, considerations of ease of insertion, availability, and avoidance of injury to coronary vessels should be the overriding factors in choosing a site for insertion of the electrodes.

The placement of the sutures and the method of insertion are shown in Figure 13. The points of penetration and emergence of the sutures on the myocardial surface should correspond to the four predrilled holes on the electrode plate.

A stab wound is then made into the myocardium at the prospective site of insertion of the electrode tip. This stab wound must be placed accurately in relation to the suture holes, so that when the electrode plate is anchored by tying the sutures, no angulation is imposed upon



Figure 13. Placement of Sutures, Fixation of Electrode Heads on Ventricular Myocardium.

the electrode tip. Note that the electrode pin emerges from the electrode plate at a point closer to the distal drill holes than the proximal ones. This relationship must be preserved in making the stab wound. The depth of the stab wound should correspond to the length of the electrode pin (5 to 7 mm). The axis of this stab wound should be perpendicular to the surface of the heart, as shown in Figure 13. The electrode is then lightly grasped with a gallbladder forceps as shown, the pin is pushed into the stab wound, and the electrode is held in this location with the forceps while the sutures are tied down.

It is important to avoid bending and angulation of the electrode pin during this process. Deformation and correction of a bend in this area can lead to metal fatigue and creation of a point of weakness in a critical area of the electrode structure, although these possibilities have been minimized by the extended core in the electrode tip.

Accurate placement of the suture and of the stab wound can be greatly facilitated by controlling the heart rate with a catheter electrode. This is accomplished by driving the heart for a few minutes at a slightly faster rate (between 80 and 100 beats/minute). When pacemaking is then interrupted for a few seconds, a brief period of asystole will result. During this interval, the sutures can be placed and the pin pushed in while the myocardium is motionless.

The silicone rubber sleeve which extends part way down on the electrode pin *should not be shortened* since it acts as an electrical insulator and contributes to formation of a narrow, high density current path between the tips of the electrodes in the depth of the myocardium. The sutures should be tied just snugly enough to hold the electrodes in place. Exaggerated tension will lead to cutting of the myocardial tissue by the suture.

Closure of Pericardium, Electrode Path

We have covered the two electrode heads with a piece of polyvinyl alcohol surgical sponge, approximately 3 to 5 mm thick and about 5 cm square.* The pericardium is then closed over this patch; this contributes enough pressure to hold the electrode securely in place until an envelope of fibrous tissue forms around the silicone material. The patch may be cut and shaped with scissors or knives; it should be soaked in sterile isotonic solution before use, to make it soft and pliable.

Sutures should not be placed around the electrode leads except for those through the predrilled holes in the electrode plate. The electrode must accommodate to some elongation during respiratory and cardiac motion; placement of extra sutures would interfere with this. Moreover, it is unnecessary, since a tight sleeve of collagenous tissue will form around the electrode heads and sleeves and will hold them firmly in place.

It is most important that sufficient length of the electrode lead be left in the chest to form a loose loop approximately as shown in Figure 14. This loop should lie on the mediastinal pleura and should rise to some distance. The electrode leads should then descend in a gentle slope towards the proximal portion of the pericardial incision.

Connecting the Electrode

Following the procedure on page 5, insert the terminal plug securely in the pulse generator receptacle. After tightening the Allen screw over the terminal pin, the proper nylon screw is used to fill and insulate the connection (match the + or - on the screw head with the + or - on the

*Furnished with the pacemaker. See page 1.

side of the pulse generator). The screw head and the adjacent area of the pulse generator may be covered with medical adhesive to make the insulation complete.

Myocardial Irritability, Ectopic Activity

As soon as the heart is electrically pacemaded (either preoperatively if a temporary electrode has been placed, or during the operative procedure after connection of the second electrode terminal), myocardial irritability manifested by ventricular complexes originating from foci other than the artificial pacemaker should be suppressed by the administration of procaine amide. This drug, even at high doses, produces only a small increase in the threshold current required to pacemake the heart. This increase is well within the margin required, provided the heart is electrically paced.

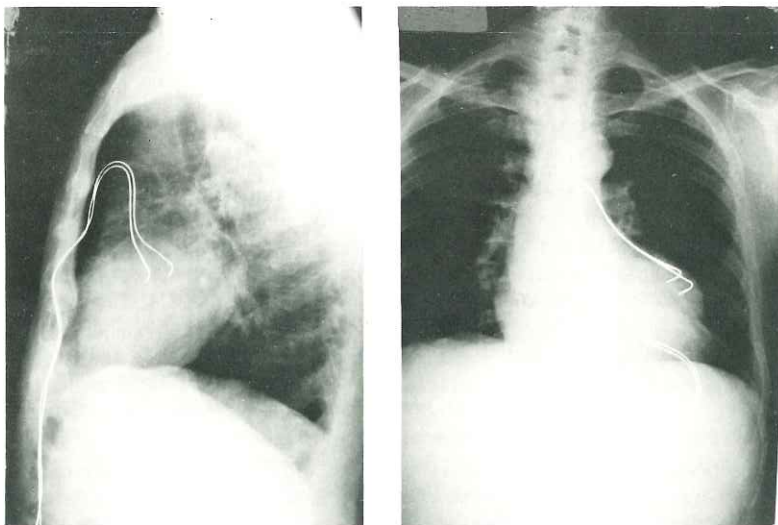


Figure 14. X-Rays Showing Proper Electrode Lead Path (Leads Retouched for Reproduction). Note High Strain-Relieving Loop.

Implantation of Pulse Generator, Closure

After insertion of the electrodes, a pocket to accommodate the pulse generator is formed in the subcutaneous tissue of the left upper quadrant, just superficial to the fascia. This pocket should hold the pulse generator snugly, but should not be unduly large in order to avoid rotation and twisting of the unit within the pocket. Approximation of the

subcutaneous tissue between the two limbs of the electrode-pulse generator terminals, by a suture or two, will also minimize rotation of the unit in too spacious a pocket. This pocket should be high in the right upper quadrant, close to the costal margin, and as medial as possible. This avoids inordinate displacement of the unit within the body, which might occur if it is placed too low in the abdominal wall.

The abdominal pocket is drained for 24 hours by a small catheter introduced through a stab wound and kept on mild suction, to avoid accumulation of blood and fluid around the pacemaker. The abdominal wound is closed in layers. During closure, care must be taken not to puncture or injure the electrode lead sleeves with the suturing needle.

A compression bandage and an abdominal binder are recommended for two to three weeks until sufficient fibrous tissue accumulates around the pacemaker to hold it in place. We have used prophylactic antibiotic therapy. Occasionally, some fluid will accumulate in the subcutaneous pocket around the pacemaker and will require aspiration.

A review of the postoperative care and topics related to pacemaking in general is outside the scope of these remarks. For additional details, the reader is referred to two publications from our group included in the list of references.

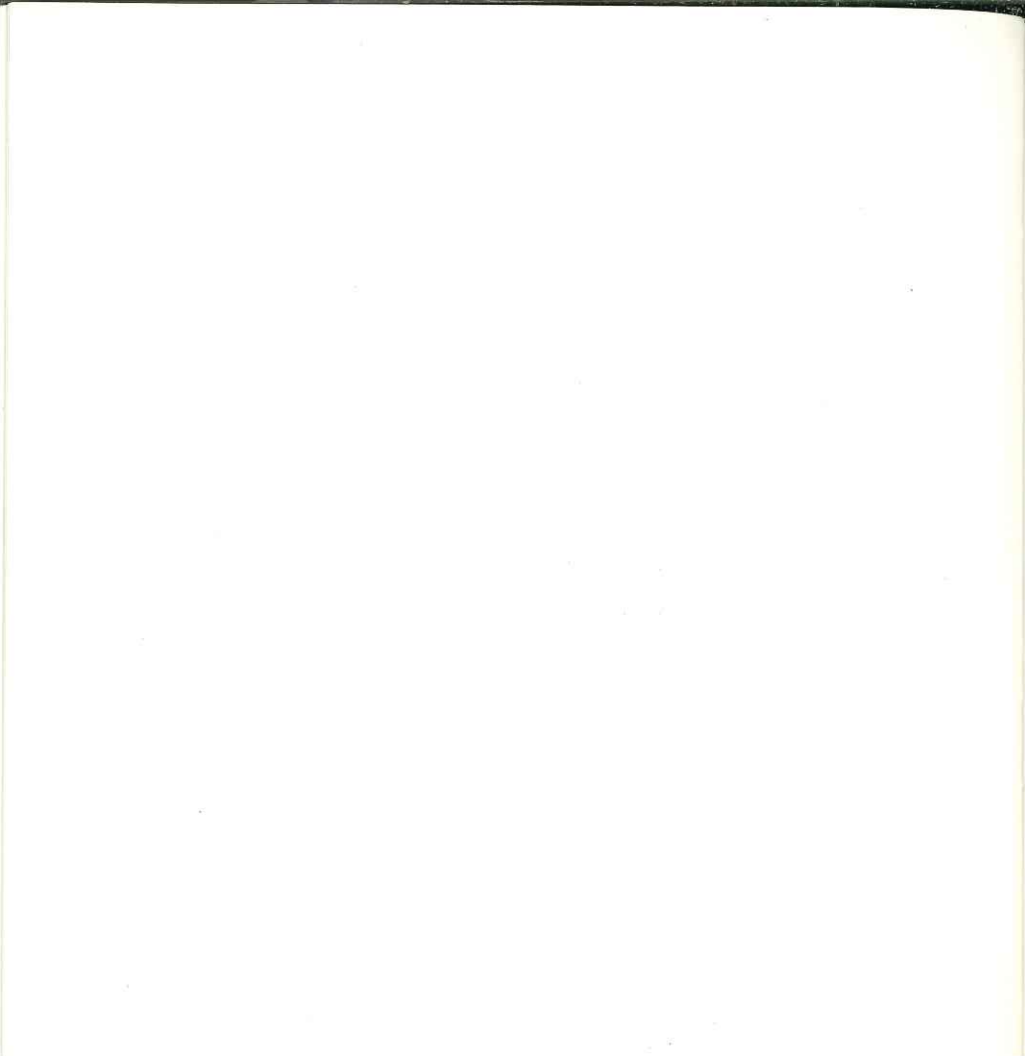
Concluding

The foregoing techniques and procedures are those used by us in our own practice. Different approaches have been reported and undoubtedly many more modifications have been used to adapt to the requirements of specific clinical situations. In considering various techniques and possibilities for the insertion of the electrode and the placement of the pulse generator, the following two general concepts should be taken into account. First, the dimensions of the electrode pin have been designed for placement into the heavy left ventricular myocardium, and ordinarily

are not suitable for the thin right ventricular wall. Second, whatever operative approach is being used, it should allow installation of the electrode leads in an adequate strain-relieving loop on the mediastinal surface. Sharp kinks and bends of the leads should be avoided.

In summary then, the following have been found to be of importance in the management of patients by thoracotomy and insertion of myocardial electrodes:

- Routine preoperative control of the heart rate by an indwelling temporary endocardiac electrode, permitting correction of congestive failure and leisurely preparation of the patient for operation.
- A fast rate of stimulation (80 to 100) during operation which, when suddenly interrupted, provides controlled periods of asystole, thus facilitating meticulous installation of the electrode system.
- Electrode lead installation involving a strain-relieving loop rising on the mediastinal pleural surface.²
- Formation of a snug pocket for the pulse generator in the abdominal subcutaneous tissue, as close to the costal arch and as medial as possible, to minimize stresses from body motion.
- Suppression of postoperative multifocal arrhythmias by procaine amide; correction of electrolyte imbalance; and, if necessary, a temporary increase of the rate.



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PULSE GENERATOR REPLACEMENT

When it becomes necessary to replace the pulse generator, we suggest the following procedure. The section numbers refer to corresponding sections of a motion picture, "Replacement of the Chardack-Greatbatch Implantable Cardiac Pacemaker", available from Medtronic.

1. Excise the pulse generator and free enough of the electrode to permit manipulation. The electrode wires should be handled with care to avoid stretching or deforming them. Cut away any medical adhesive from the setscrew area and expose the setscrews (Figure 15).

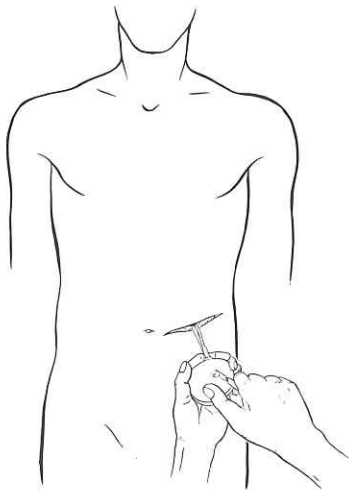


Figure 15. Pacemaker Exteriorized for Replacement

2. Free the electrode terminals by cutting away the medical adhesive and the silicone rubber boot. With the knife parallel to the electrode, cut toward the body of the pulse generator. The blade will stop at the hard epoxy under the silicone rubber capsule. Deflect the knife outward and away from the electrode terminal (Figure 16). *Do not cut into the electrode terminals.* A nick in the electrode or its conductor will provide a focal point for stress and will lead to later fracture at that point. Completely expose both electrode plugs by cutting around each plug.

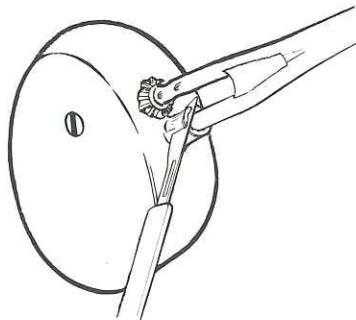


Figure 16. Proper Trimming Angle

3. Remove the nylon filler screws and stainless-steel setscrews (Figure 17). Gently remove the electrode terminal from the negative socket. It may be necessary to sever some remaining medical adhesive by carefully passing a small blade (B-P No. 11) around the nylon sleeve just within the lip.

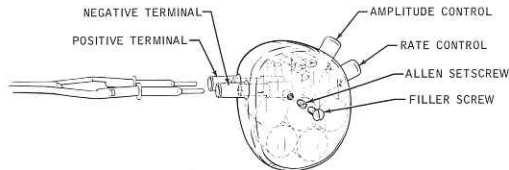


Figure 17. Assembly of Terminal Setscrews

4. Using a sterile clip lead, connect the negative electrode terminal to the negative post of an external, battery-powered, calibrated pacemaker (Medtronic Model 5800). Connect the positive post of the pacemaker to some instrument in contact with the subcutaneous tissue. Advance the current control until capture is secured and record the threshold.
5. Remove the second electrode terminal from the excised pulse generator. Connect this terminal to the negative post of the external pacemaker and record the threshold.
6. Trim remaining medical adhesive from the electrode terminals. Avoid cutting into the plug of the electrode, but remove enough material so that the plug can be inserted into the fresh pulse generator.
7. The fresh pulse generator may now be connected. First, remove the filler screws from the setscrew holes and note that the plus sign or minus sign on the screwhead matches the sign on the side of the pulse generator.
8. Select the electrode terminal showing the lower threshold or, if the thresholds are essentially the same, the terminal with teflon rings imbedded in the silicone rubber. This terminal is inserted in the

negative receptacle. After checking to see that the electrode terminal pin is clearly visible through the setscrew hole, the setscrew is tightened down on the pin. Do not remove the wrench from the seated setscrew.

During this portion of the procedure pacing is maintained with the external pacemaker, which is connected to the other electrode terminal and to the indifferent electrode.

9. Quickly transfer the sterile clip lead from the uninserted electrode terminal to the Allen wrench. The patient is still being paced from the external pacemaker, via the Allen wrench, setscrew, and connected electrode. The circuit is shown in Figure 18.

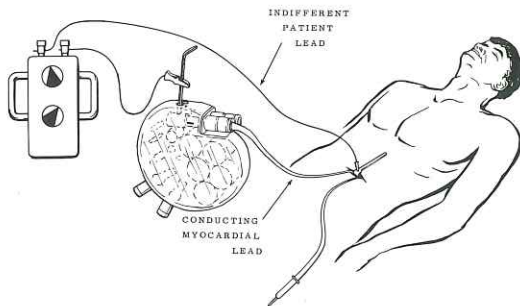
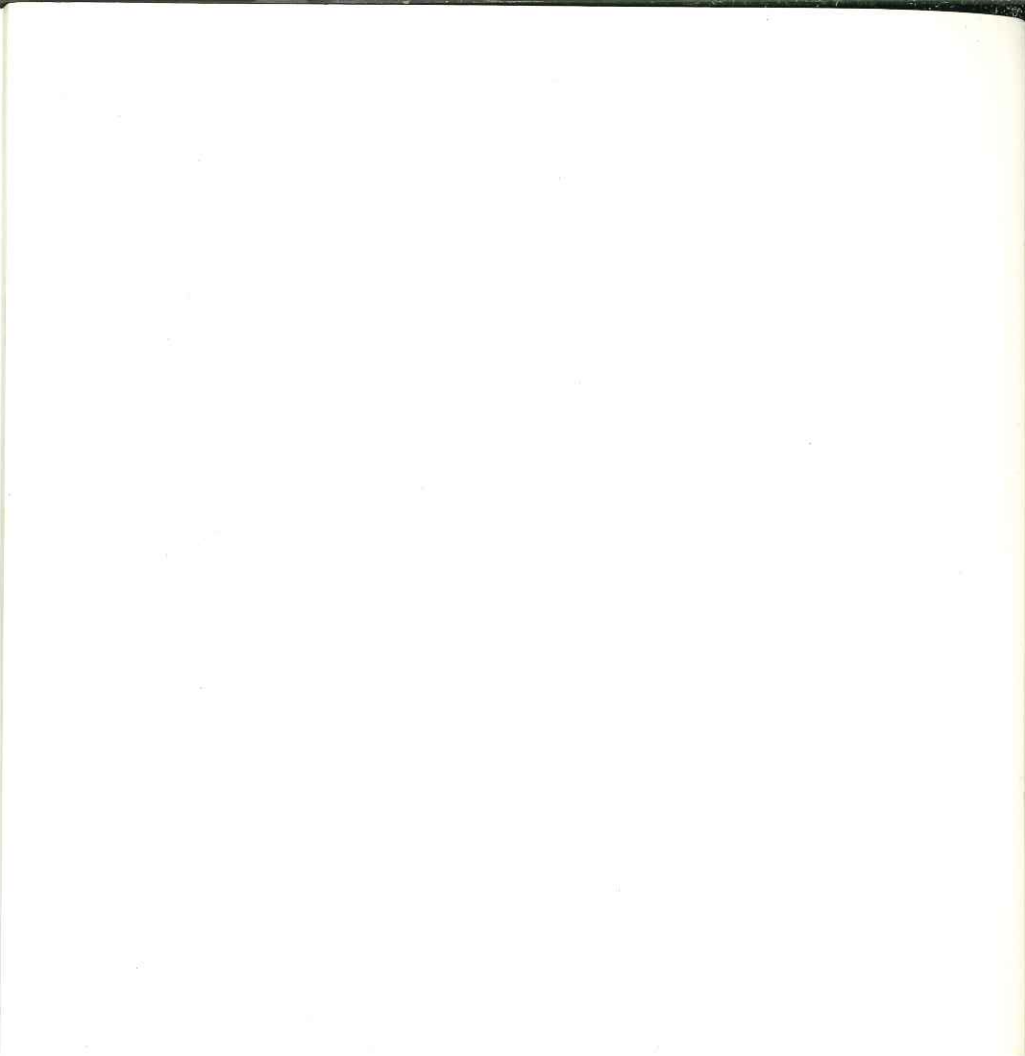


Figure 18. Temporary Pacing Circuit

10. The second electrode terminal is plugged into the positive receptacle of the pulse generator. As soon as this electrode is inserted, the external pacemaker should be disconnected. If this is not done the patient will be receiving stimuli from two pacemakers.

The remainder of the connection procedure is covered on page 5.

APPENDIX



SPECIAL PULSE GENERATORS

The pulse generators described in this section—Models 5852, 5860, 5860-C, and 5868—are available on special order, and are occasionally required by special clinical circumstances. Except for the specific differences discussed below, the general design characteristics, handling, and implantation of these units are as described in the main body of this manual for the Model 5870-C. If further information on these units is desired, contact your local Medtronic representative, or the Medtronic home office.

Model 5852

This unit has nonadjustable rate and can be supplied preset to any rate between 55 and 120 bpm. Output amplitude is adjustable (see p. 47) from 0 to 23 ma (11.5 v across a 500 Ω load), measured 0.5 milliseconds after the leading edge of the pulse. This model is normally supplied with the output set at 10 ma. The circuitry includes a transistorized voltage doubler to produce the high output needed by some patients. Power supply is five mercury cells. Because of the increased power drain on these cells due to the voltage doubling action, the anticipated battery life is two years at the factory setting. Higher output settings will further reduce battery life expectancy. At maximum output, the anticipated battery life is about 14 months.



Figure A. Model 5852 Implantable Pulse Generator

Model 5860

This unit has nonadjustable rate and current. It is available with any rate between 55 and 120 bpm. Output amplitude is 4 ma (2 volts across a 500Ω load), measured 0.5 milliseconds after the leading edge of the pulse. This output may be increased (at the cost of increased current drain from the batteries) by appropriate use of the utility extension (see page 44). The power supply consists of six mercury cells, as compared with the five used in the Models 5852 and 5870-C.

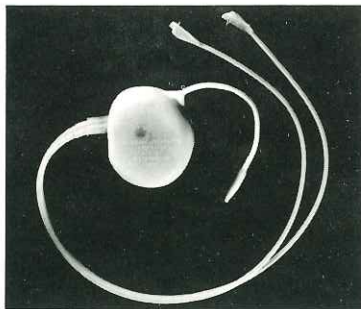


Figure B. Model 5860 Implantable Myocardial Pacemaker

Model 5860-C

This unit has nonadjustable rate and current. It is available with any rate between 55 and 120 bpm. Output amplitude is 14 milliamps, or 7 volts across a 500Ω load, measured 0.5 msec after the leading edge of the pulse. There is no provision for changing this amplitude. The power supply consists of six mercury cells.

Model 5868

This unit has nonadjustable rate-it can be supplied with any preset rate between 55 and 120 bpm. Current is adjustable from 0 to 13.6 ma (6.8 v across 500Ω). Except for the lack of a rate control, it is identical to the 5870-C. It has no safety extension.

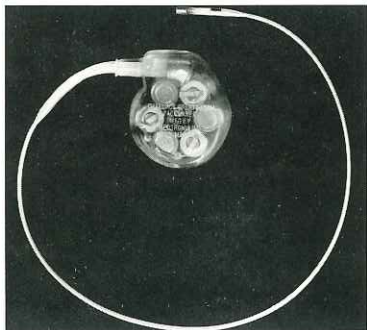


Figure C. Model 5860-C Implantable Pulse Generator



Figure D. Model 5868 Implantable Pulse Generator

The Safety Extension (Model 5860)

The safety extension is a capped silicone rubber tube containing three wires. Its purpose is to provide rapid access to the pacemaker circuit without having to exteriorize the entire unit. The slightly bulbous silicone rubber cap of the extension can be palpated beneath the skin. Under local anesthesia, an incision is made a few centimeters proximal to the cap, over the sleeve. This enables one to exteriorize the distal portion of the extension without pulling on it. The cover is removed and the teflon insulation is stripped from the distal centimeter of the wires. The connections of the extension wires to the circuitry of the pulse generator are shown in Figure E.

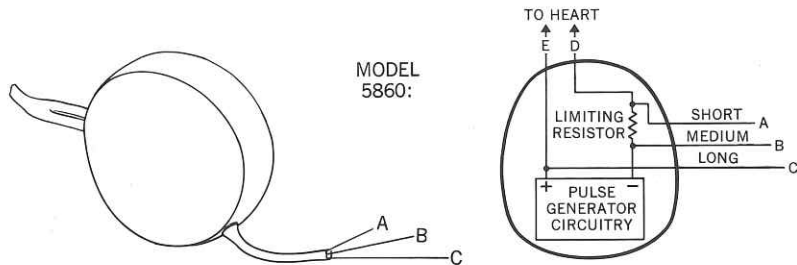


Figure E. Safety Extension Wires, Identification by Length and Connections to Circuit

To Repair and Reseal the Safety Extension

A new cover* is filled with medical adhesive and pushed over the wires. When the cover is being filled with adhesive, squeeze it between thumb and index finger, and release pressure as medical adhesive fills cover. This prevents the inclusion of air bubbles. When the cover is

*Medtronic Part No. 5860-15, furnished with Service Kit No. 5865.

filled, push the wires from the extension into the medical adhesive, and carefully slide the cover over the remaining portion of the silicone rubber sleeve. After removal of excessive adhesive, a suture may be tied around the rim of the cover. The safety extension may be replaced immediately; the medical adhesive will continue to set after implantation.

Precautions To Be Taken When the Safety Extension is Used

The wires of the safety extension are in direct connection with the myocardial electrodes-hence, care must be exercised when ac-powered equipment is brought into contact with these wires. Soldering irons should never be applied to them. Splicing the wires by twisting, with or without use of the clips supplied, should provide adequate electrical contact. Even line-powered pacemaking equipment can be dangerous since minute 60-cycle ground currents (on the order of 100 microamps) can produce ventricular fibrillation.¹⁶ This is particularly apt to occur when the patient is connected to several pieces of line-powered equipment, such as a monitor or electrocardiograph, etc., or is otherwise grounded by contact with an x-ray table or a metallic bed frame. The best precautionary measure against accidental leakage currents is to use only battery-driven pacemakers. If this type is unavailable and an ac-powered external pacemaker must be used in an emergency. *It should be the only line-powered equipment in contact with the patient.* This does not provide complete protection against accidental grounding through an x-ray table or bed frame, etc., but at least reduces the grave risks inherent in the use of multiple line-powered equipment. It is of course possible to check the output and function of an implantable pacemaker by connecting the wires of the safety extension (wires A and C) to an oscilloscope, but again the same danger of fibrillation exists when this is done, and must be guarded against by appropriate grounding and checking of the equipment by competent personnel.

Appendix

<u>Model</u>	<u>To Disable the Pacemaker</u>	<u>Emergency Pacing with External Pacemaker</u>	<u>To Increase Output</u>
5852, 5868, and 5870-C	Turn amplitude control to null (or rate control on 5870-C).	1. Disable the Pacemaker 2. Connect sterile leads to Allen setscrews (see Replacement, p. 38)	Adjust amplitude control
5860	Splice wires B & C of the utility extension	1. Disable the Pacemaker 2. Connect sterile leads to setscrews, or Connect sterile leads to indifferent electrode and splice of wires B & C.	Splice wires A & B of the utility extension
5860-C	Disconnect the pulse generator from the electrode.	1. Disable the Pacemaker 2. Connect sterile leads to the electrode.	No provision

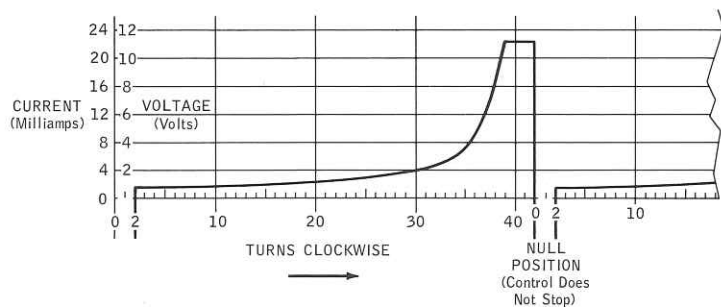


Figure F. Output Current into Test Load vs Control Setting for Model 5852

SUPPLEMENTAL INFORMATION

Supplemental information (including information on pulse generator replacement and motion pictures of the operative procedures) may be obtained from your local Medtronic representative or directly from the Medtronic home office.

Write: Medtronic, Inc.
3055 Old Highway Eight
Minneapolis, Minnesota 55418 USA

Phone: Area 612/781-6855
Consultation is available 24 hours a day, 7 days a week.

European Service Center:

Schiphol Airport East, Building 144
The Netherlands

Phone: 020-157495

Telex: 14498



LIMITATION OF WARRANTY—REPLACEMENT CREDIT AGREEMENT

Please Read Carefully

1. In spite of the care employed in the design of circuitry, the selection of components, the manufacturing process, and the checking and testing prior to acceptance as a finished product, some Chardack-Greatbatch Implantable Cardiac Pulse Generators will fail in the extremely hostile environment of the human body. Therefore, Medtronic, Inc. does not assume any liability for malfunctions from any cause other than to the extent set forth in this Replacement Credit Agreement. Nor does Medtronic, Inc. warrant or guarantee the Chardack-Greatbatch Implantable Cardiac Pulse Generator for any specific length of time.

2. In the event of Chardack-Greatbatch Implantable Cardiac Pulse Generator malfunction due to structural defect, component failure or battery exhaustion within three (3) years of the original date of implantation, a pro-rata credit will be allowed against the purchase price of a new Chardack-Greatbatch Implantable Cardiac Pulse Generator, but only when said purchase is made for replacement in the same person. For each full month of service less than three (3) years, an amount equal to 1/36th of the lower of the original or replacement purchase price (per Medtronic, Inc.'s published U.S.A. price schedule) will be allowed on the replacement Chardack-Greatbatch Implantable Cardiac Pulse Generator; provided, however, that for service of less than twelve (12) months an amount equal to the lower of the original or replacement purchase price (per Medtronic, Inc.'s published U.S.A. price schedule) will be allowed on the replacement Chardack-Greatbatch Implantable Cardiac Pulse Generator.

3. For Chardack-Greatbatch Implantable Cardiac Pulse Generators returned without defect, but otherwise qualifying for replacement credit under paragraph 2 above, one-half (1/2) of the pro-rata credit stated therein will be allowed.

4. Determination of Chardack-Greatbatch Implantable Cardiac Pulse Generator defect will be made by Medtronic, Inc. at Minneapolis, Minnesota, U.S.A., after inspection of the returned unit. Units returned for consideration of credit allowance shall become the property of the manufacturer.

5. Prompt return of the removed Chardack-Greatbatch Implantable Cardiac Pulse Generator accompanied by complete circumstantial information is of essence for credit determination. Medtronic, Inc. will evaluate and determine the credit allowance, if any, upon receipt of the returned unit and complete circumstantial information.

6. Chardack Heart Electrodes used with the Chardack-Greatbatch Implantable Cardiac Pulse Generator are excluded from this Replacement Agreement because their structure may be damaged by improper handling either before or during insertion. For this reason, Medtronic, Inc. cannot warrant the Chardack Heart Electrode but may elect, at its discretion, to furnish replacement Chardack Heart Electrodes at no charge when this appears justified. Used Chardack Heart Electrodes returned shall become the property of the manufacturer.

The Replacement Credit Agreement herein outlined is in lieu of all warranties, expressed or implied, and all other obligations on its part, and Medtronic, Inc. neither assumes nor authorizes any other person to assume for it, any other liability in connection with the sale or use of the Chardack-Greatbatch Implantable Cardiac Pulse Generator or Chardack Heart Electrodes. There are no warranties which extend beyond the terms hereof.